Package leaflet: Information for the user

CO-DYDRAMOL TABLETS

(dihydrocodeine tartrate and paracetamol)

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

This medicine contains dihydrocodeine which is an opioid, which can cause addiction. You can get withdrawal symptoms if you stop taking it suddenly.

1. What Co-dydramol Tablets are and what are they used for

Co-dydramol tablets belong to a group of medicines called analgesics and are used for the relief of mild to moderate pain. They contain the active ingredients dihydrocodeine tartrate and paracetamol which belong to a group of medicines called strong analgesics or 'painkillers'.
This medicine has been prescribed for you to treat mild to moderate pain. It contains dihydrocodeine which belongs to a class of medicines called opioids, which are 'pain relievers'.
This medicine has been prescribed to you and should not be given to anyone else. Opioids can cause addiction and you may get withdrawal symptoms if you stop taking it suddenly. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.

2. What you need to know before you take Co-dydramol Tablets

Do not take Co-dydramol Tablets and tell your doctor if you:
- Are allergic to dihydrocodeine, other opioids, paracetamol or any of the other ingredients this medicine (see section 6 'Contents of the pack and other information');
- Have difficulty breathing, or other chronic lung disease;
- Are having an asthma attack;
- Have diarrhoea caused by poisoning or severe bloody diarrhoea (pseudomembranous colitis).
- Have liver disease.

Warnings and Precautions
Talk to your doctor or pharmacist before taking this medicine if you have:
- Liver or kidney problems;
- Diseased adrenal glands (Addison's disease) or high blood pressure caused by a tumour near a kidney (phaeochromocytoma);
- Inflammatory bowel disease;
- Gall bladder disease or gall stones;
- Recently had surgery on your gastro-intestinal tract or urinary system;
- An enlarged prostate gland and have difficulty urinating and are male;
- Epilepsy or suffered head injury or raised pressure in the skull (may cause painful eyes, changes in vision or headache behind the eyes);
- An underactive thyroid gland;
- Muscle weakness (myasthenia gravis);
- Low blood pressure or are in shock;
- Suffered from alcoholism, drug abuse or dependence or mental illness.
- are or have ever been addicted to opioids, alcohol, prescription medicines, or illegal drugs.
- have previously suffered from withdrawal symptoms such as agitation, anxiety, shaking or sweating, when you have stopped taking alcohol or drugs.
- feel you need to take more of Co-dydramol to get the same level of pain relief, this may mean you are becoming tolerant to the effects of this medicine or are becoming addicted to it. Speak to your prescriber who will discuss your treatment and may change your dose or switch you to an alternative pain reliever.

Taking this medicine regularly, particularly for a long time, can lead to addiction. Your prescriber should have explained how long you will be taking it for and when it is appropriate to stop, how to do this safely.
Rarely, increasing the dose of this medicine can make you more sensitive to pain. If this happens, you need to speak to your prescriber about your treatment.
Addiction can cause withdrawal symptoms when you stop taking this medicine. Withdrawal symptoms can include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, loss of appetite, shaking, shivering or sweating. Your prescriber will discuss with you how to gradually reduce your dose before stopping the medicine. It is important that you do not stop taking the medicine suddenly as you will be more likely to experience withdrawal symptoms.
Opioids should only be used by those they are prescribed for. Do not give your medicine to anyone else. Taking higher doses or more frequent doses of opioid, may increase the risk of addiction. Overuse and misuse can lead to overdose and/or death.

Talk to your doctor at once if you take too much of this medicine even if you feel well. This is because too much paracetamol can cause delayed serious liver damage.
Do not take the tablets for longer than as directed by your doctor. Taking dihydrocodeine regularly for a long time can lead to addiction which might cause you to feel restless and irritable when you stop the tablets. Taking a painkiller for headaches too often or for too long can make the headache worse.
During treatment with Co-dydramol Tablets, tell your doctor straight away if:
- you have severe illnesses, including severe renal impairment or sepsis (when bacteria and their toxins circulate in the blood leading to organ damage), or you suffer from malnutrition, chronic alcoholism or if you are also taking flucloxacillin (an antibiotic). A serious condition called metabolic acidosis (a blood and fluid abnormality) has been reported in patients in these situations when paracetamol is used at regular doses for a prolonged period or when paracetamol is taken together with flucloxacillin. Symptoms of metabolic acidosis may include: serious breathing difficulties with deep rapid breathing, drowsiness, feeling sick (nausea) and being sick (vomiting).

Other medicines and Co-dydramol Tablets
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including medicines obtained without a prescription. In particular, tell your doctor or pharmacist if you are taking any of the following medicines:
- Ciprofloxacin (antibacterial medicine);
- Monoamine Oxidase Inhibitors (MAOIs, e.g. moclobemide or have taken these within the last 2 weeks);
- Oral contraceptives (the "pill");
- Medicines to prevent blood clotting such as warfarin;
- Cyclizine, metoclopramide or domperidone (to prevent sickness);
- Guanethidine or diuretics ("water tablets") e.g. spironolactone, furosemide (to treat high blood pressure);
- Mexiletine (to treat irregular heartbeats);
- Loperamide or kaolin (to treat diarrhoea);
- Selegiline (for Parkinson's disease);
- Phenytoin (to treat epilepsy);
- Cimetidine (to treat stomach ulcers);
- Atropine or hyoscine (anticholinergic medicines);
- Cisapride (to treat gastro-oesophageal reflux disease);
- ritonavir (antiviral medicine);
- Medicines which affect the nervous system such as sleeping tablets, diazepam, hydroxyzine and medicines to treat mental illness;
- Medicines to treat depression (e.g. tranylcypromine, amitriptyline);
- Medicines which affect the liver (e.g. primidone and rifampicin);
- Colestyramine (to treat high cholesterol levels);
- Muscle relaxants;
- Barbiturates (e.g. phenobarbital);
- Anaesthetics;
- Opioid antagonists (buprenorphine, naltrexone, naloxone).
- Flucloxacillin (antibiotic), due to a serious risk of blood and fluid abnormality (called metabolic acidosis) that must have urgent treatment (see section 2).

Concomitant use of Co-Dydramol Tablets and sedative medicines such as benzodiazepines or related drugs increases the risk of drowsiness, difficulties in breathing (respiratory depression), coma and may be life-threatening. Because of this, concomitant use should only be considered when other treatment options are not possible.
However if your doctor does prescribe Co-Dydramol Tablets together with sedative medicines the dose and duration of concomitant treatment should be limited by your doctor.
Please tell your doctor about all sedative medicines you are taking, and follow your doctor's dose recommendation closely. It could be helpful to inform friends or relatives to be aware of the signs and symptoms stated above. Contact your doctor when experiencing such symptoms.

Co-dydramol with food, drink and alcohol
If your diet is poor or you have a low protein intake, you may be at a higher risk of serious paracetamol poisoning when taking Co-dydramol tablets.
Do not drink alcohol whilst taking Co-dydramol tablets.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.
If you use this medicine during pregnancy, your baby may become dependent and experience withdrawal symptoms after the birth which may need to be treated.
Do not take this medicine while you are breastfeeding as dihydrocodeine passes into breast milk and will affect your baby.

Driving and using machines
Co-dydramol tablets may cause dizziness, blurred vision or the inability to think clearly. Make sure you are not affected before you drive or operate machinery.

The medicine can affect your ability to drive as it may make you sleepy or dizzy.
- Do not drive while taking this medicine until you know how it affects you.
- It is an offence to drive if this medicine affects your ability to drive.

- However, you would not be committing an offence if:
- The medicine has been prescribed to treat a medical or dental problem and
- You have taken it according to the instructions given by the prescriber or in the information provided with the medicine and
- It was not affecting your ability to drive safely

Talk to your doctor or pharmacist if you are not sure whether it is safe for you to drive while taking this medicine.

Information on sodium content
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Co-dydramol Tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
Swallow the tablets with water, during or after meals.
Co-dydramol tablets are normally used only for short-term relief of symptoms. Take this medicine for as long as your doctor tells you to, it may be dangerous to stop without their advice.

Your prescriber should have discussed with you, how long the course of this medicine will last. They will arrange a plan for stopping treatment. This will outline how to gradually reduce the dose and stop taking the medicine.

The recommended dose is:
Adults: 1 to 2 tablets every 4 hours up to a maximum of 8 tablets in a day.
Elderly: Dosage is usually reduced in the elderly.
Use in children and adolescents:
- Children 16-18 years: 1 to 2 tablets every 4 hours up to a maximum of 8 tablets in 24 hours.
- Children 12-15 years: 1 tablet every 4-6 hours when necessary up to a maximum of 4 tablets in 24 hours.
- Children under 12 years: Not recommended.

If you take more Co-dydramol Tablets than you should:
If you (or someone else) swallow a lot of tablets at the same time, or you think a child may have swallowed any contact your nearest hospital casualty department or tell your doctor immediately. Symptoms of an overdose include feeling or being sick, loss of appetite, abdominal/stomach pain or liver damage, coma, clammy skin, fits, confusion, drowsiness, tiredness, low blood pressure, pinpoint pupils, slow heart beat or breathing rate.

If you forget to take Co-dydramol Tablets:
If you miss a dose you should take it as soon as you remember and then carry on as before. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Co-dydramol Tablets:
Do not suddenly stop taking this medicine. If you want to stop taking this medicine, discuss this with your prescriber first. They will tell you how to do this, usually by reducing the dose gradually so that any unpleasant withdrawal effects are kept to a minimum. Withdrawal symptoms such as restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating may occur if you suddenly stop taking this medicine.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Please tell your doctor or pharmacist if you notice any of the following effects or any effects not listed.

Contact your doctor at once if the following side effects occur:
Rare (may affects up to 1 in 1,000 people)
- Allergic Reactions - skin rash or itchy skin, difficulty breathing, increased sweating, redness or flushed face, mucosal lesions (such as mouth ulcers), drug fever;

Very rare (may affect up to 1 in 10,000 people):
- Severe stomach pain, which may reach through to your back. This could be a sign of inflammation of the pancreas (pancreatitis).
- Cases of serious skin reactions have been reported.

Not Known (frequency cannot be estimated from available data)
- Anaphylactic shock, swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing.
- Reddish target-like spots or circular patches often with central blisters on the trunk. Ulcers of mouth, throat, nose, genitals and eyes (red and swollen eyes), fever and/or flu-like symptoms can occur (Toxic epidermal necrolysis or Stevens-Johnson syndrome, acute generalised exanthematous pustulosis, fixed drug eruption). The rashes may progress to widespread peeling of the skin and life-threatening complications or be fatal.
- Abdominal pain caused by spasm of the bile ducts and inflammation of the liver.
- A serious condition that can make blood more acidic (called metabolic acidosis), in patients with severe illness using paracetamol (see section 2).

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

Not known (frequency cannot be estimated from available data):
- Gastrointestinal system - stomach irritation (mild stomach pain, heartburn and feeling sick), constipation, feeling or being sick, loss of appetite, abdominal pain, dry mouth, difficulty in the passage of food through guts;
- Heart - slow heart rate, palpitations, low blood pressure especially on standing, inflammation of the heart muscle;
- Blood - anaemia, changes in numbers and types of blood cells. If you have an increase in number of nose bleeds or notice that you bruise more easily or have more infections talk to your doctor;
- Urinary system - pain and difficulty in passing urine and a less frequent need to do so, kidney problems;
- Nervous system - confusion, drowsiness, dizziness, 'spinning' sensation, mood changes, depression, hallucinations (seeing or hearing things that are not real), restlessness, excitation, fits, increased pressure in the skull (painful eyes, changes in vision or headache behind the eyes), headache, difficulty sleeping, nightmares, reduced alertness. Tolerance (medicine has less effect) or dependence and addiction (see section "How do I know if I am addicted?").
- Eyes - blurred or double vision, extremely small pupils;
- Skin - Very rare cases of serious skin reactions have been reported;
- Others - trembling, unusual tiredness or weakness, malaise, low body temperature, breathing difficulties, muscle stiffness.

Drug Withdrawal
When you stop taking this medicine, you may experience drug withdrawal symptoms, which include restlessness, difficulty sleeping, irritability, agitation, anxiety, feeling your heartbeat (palpitations), increased blood pressure, feeling or being sick, diarrhoea, shaking, shivering or sweating.

How do I know if I am addicted?
If you notice any of the following signs whilst taking this medicine, it could be a sign that you have become addicted.
- You need to take the medicine for longer than advised by your prescriber
- You feel you need to use more than the recommended dose
- You are using the medicine for reasons other than prescribed
- When you stop taking the medicine you feel unwell, and you feel better once taking the medicine again

If you notice any of these signs, it is important you talk to your prescriber.
If any of the above side effects are troublesome or last more than a few days or if you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/ yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Co-dydramol Tablets

- Keep this medicine out of the sight and reach of children.
- Store below 25°C. Protect from light and moisture.
- Do not use Co-dydramol tablets after the expiry date on the carton, pot and blister. The expiry date refers to the last day of that month.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Co-dydramol Tablets contain:
- The active substances are paracetamol and dihydrocodeine tartrate. Each tablet contains 500 mg of paracetamol and 10 mg of dihydrocodeine tartrate.
- The other ingredients are: starch, polyvinylpyrrolidone, sodium starch glycollate, stearic acid, colloidal silicon dioxide, talc and potable water.

What Co-dydramol Tablets look like and contents of the pack
- Co-dydramol Tablets are white, flat, bevel edge tablets with plain on one face and break line on the other.
- Co-dydramol Tablets are available in pots of 10, 12, 20, 24, 25, 30, 50, 100, 250, 500 or 1000 tablets and blisters of 30 or 100 tablets.
- Not all pack sizes may be marketed.

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